

Data privacy in clinical research

Research in medicine can be of two kinds. 'Basic' research is done usually in the lab by individuals who are trained to examine specific questions using experimental rodents (rats and mice) or cell cultures. Clinical research is research that involves human patients. Clinical research could be done to test for new drugs or to look at patterns in data that has already been collected (this is called a 'retrospective' study). Clinical research plays the most important part in developing new therapies for people with neurological (or any) illness. Some diseases have very few effective treatment options; for these, clinical research is the only way we can ensure better therapies for future patients.

The process of bringing a new drug to patients is long and expensive. Only one out of 5000 – 10000 potential new drugs is ultimately approved by the Food and Drug Association (FDA) for use in the clinic. Each clinical trial has eligibility criteria which differ according to the type of study being done; and all participants are willing volunteers who go through an extensive consent process to make sure they understand their role and any potential risks. Participants are free to end their participation in the study any time they wish.

One of the important issues in clinical research is that of **data privacy**. What is data privacy, and what is being done to ensure that human data is kept safe?

- Data obtained as a result of clinical research is highly confidential. Hence, responsible storage, share and use are extremely important for clinicians and researchers. Once the data has been collected, reporting and publishing this data also can be done only by qualified professionals.
- Before (any) clinical study is initiated, clinicians / scientists are required to submit to a regulatory board a detailed plan that describes the study plan and goals. The regulatory board is called the Institutional Review Board (IRB). These proposals are approved only if the board is convinced that the study is safe, ethical and necessary.
- In addition to ensuring safety of the protocol, regulatory boards also have strict conditions for data privacy. Only certain certified individuals have access to data. Depending on the type of study, care is taken to make sure that data is de-identified (the name is replaced by a series of numbers, and researchers never know the participant's real name, only this number).
- The protocols have detailed description about record keeping and data handling. Each patient has a case report form (CRS) that is kept in a safe, locked place by a certified professional. There are strict regulations about how and where the CRSs should be kept, what to do in case corrections need to be made to the CRSs, and steps to be taken in case the CRSs need to be transported. This important document contains information on everything related to a certain individual – e.g. history, treatments received, side-effects (if any), tests done and results obtained.

